K050934

SHL MEDICAL

A subsidiary of Phase Forward Incorporated

JUN 24 2005

510(k) SUMMARY

1. Submitter

SHL Medical, USA
23 Vreeland Road, Suite 104
Florham Park, New Jersey 07932
Office Telephone: 973 822-3007

Contact Person

Lucio Giambattista
Telephone: 973 822-3007

Date of Preparation:

February 17, 2005

2. Device Information

Device Trade Name: DAI™
Device Common Name: Auto-injector
Classification Name: Introducer, Syringe Needle

3. Device to which substantial equivalence is claimed

Device Name: Owen Mumford Autoject Mini
510(k) Clearance Number: K000482
Device Common Name: Syringe needle introducer
Classification Name: Introducer, Syringe Needle

4. Device Description

DAI™ is an automatic drug delivery device that is used for the subcutaneous administration of drugs and biologics from standard 1.0mL long glass syringes with staked needle from 25g to 27g and 12.7mm in length that are prefilled prior to use in DAI™. DAI™ is a single-use, disposable, syringe needle introducer device that is spring-powered and designed to administer the entire contents of the prefilled syringe during one injection. A DAI™ injection consists of the automatic insertion of the syringe needle to a predetermined depth into the skin, followed by the automatic delivery of the syringe contents.

DAI™ consists of two subassemblies into which the syringe is loaded and connected together to form the delivery system for self injection. The assembled DAI™ has a tubular design with a needle end and a power assembly with activation button end. DAI™ components and subassemblies are made of plastic and metal. DAI™ does not have any fluid path and does not have any contact with the drug or biologic contained within the syringe.

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5. Intended Use

The Intended Use of DAI™ is for the automatic self-administration of FDA-approved drugs and biologics from standard 1.0mL Long Syringes with Needle that have been prefilled prior to use with DAI™.

6. Technological Characteristics

The technological characteristics of DAI™ are the same as other introducer products that are currently marketed in the U.S.

DAI™ is made of materials that have been evaluated for use in manufacturing medical devices, including syringe needle introducers. DAI™ uses a pre-compressed stainless steel spring that when released by the activation of the device, drives a plunger rod onto the stopper of the syringe to expel the contents and effect the injection.

Design and performance features of DAI™ include a safety mechanism to prevent inadvertent activation, automatic recovering of the used needle, cutout window on the front assembly to permit inspection of the syringe, locking tabs to prevent disassembly of DAI™ once the two subassemblies have been connected, and self-disabling after use.

No performance standards have been established for Introducer, Syringe Needle. DAI™ was assessed using the sections and methods specified in ISO 11608:2000 "*Pen injectors for medical use-Part 1: Pen injectors - Requirements and test methods*" as they apply to injection devices with non-replaceable prefilled cartridges. Activation force, needle extension, injection time, completeness of injection, functionality, and robustness were assessed; DAI™ met all requirements and specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2005

Mr. Lucio Giambattista
Managing Director
SHL Medical, USA
23 Vreeland Road, Suite 104
Florham Park, New Jersey 07932

Re: K050434
Trade/Device Name: SHL DAI™
Regulation Number: 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: June 20, 2005
Received: June 22, 2005

Dear Mr. Giambattista:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050434

Device Name: SHL DAI™

Indications for Use:

DAI™ is a hand-held mechanical device intended for the automated, subcutaneous, self-administration of FDA-approved drugs and biologics. DAI™ is designed to be used with the standard 1.0mL Long (glass) Syringe with Needle that has been prefilled prior to an injection. DAI™ is for use in the home environment to aid and support prescribed treatment and therapy.

Prescription Use __XX__ AND/OR **Over-the-Counter Use**_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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